APR 1 1 2006

K 060626

Sonomed Inc.
Special 510(k)
VuMax

510(k) Summary
February 27, 2006

(1) Submitter Information

Name: Sonomed Inc..

Address: 1979 Marcus Avenue
Lake Success, NY 11042

Telephone Number: 516-354-0900

Contact Person: Dr. George Myers
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703

Date Prepared: February 25, 2004

(2) Name of Device:
Trade Name: VuMax
Common Name: Opththalmic ultrasonic A and B scan system
Classification Name: System, Imaging, Ultrasonic, Ophthalmic, 980IYO

(3) Equivalent legally-marketed devices:

Sonomed EZ-Scan AB 5500+ , K040668

(4) Description

The VuMax High Resolution Ultrasound System is intended to be used for visualization by ultrasound of the eye and orbit by A-scan and B-scan. It is not intended to be used for determining the power of implanted ocular lenses, but it is capable of making intra-ocular measurements.

The system is PC-based, and can be used with a 35 MHz transducer (standard) or a 50 MHz transducer (optional). Because of the higher frequency of the transducers, it is expected that its greatest field of application will be in visualizing the anterior segment, because the focus area is about 11 mm from the transducer plane. The system will visualize other parts of the eye, but the resolution is not as high.

(5) Intended Use

. The VuMax High Resolution Ultrasound System is intended to be used for visualization by ultrasound of the 'e and orbit by A-scan and B-scan.

(6) Technological characteristics

The VuMax is a conventional ophthalmic A and B-scan system using a motor-driven transducer and angle sensor for scanning. The A-scan is derived from the B-scan. There is a choice of transducer frequency of 35 MHz or 50 MHz. It uses a motor-driven 10 MHz transducer with an attached angle encoder. The system is PC-based, and the display is on the computer screen.

(b) Performance data

(1) Non-clinical tests

Both ultrasonic emissions tests and accuracy and validation tests have been done.

(2) Clinical tests

Not required

(3) Conclusions

The Sonomed VuMax is equivalent in safety and efficacy to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 11 2006

SonoMed, Inc.
% Mr. George Myers
President
Medsys, Inc.
377 Route 17 S
HASBROUCK HEIGHTS NJ 07604

Re: K060626
Trade Name: VuMax
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: March 3, 2006
Received: March 17, 2006

Dear Mr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the VuMax, as described in your premarket notification:

Transducer Model Number

35 MHz transducer
50 MHz transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Page 1 of 3

510(k) Number (if known): K060626

Device Name: VuMax

Intended Use:
The *VuMax* ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye.

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic	P	P								P (3D)
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use** ____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060626

Diagnostic Ultrasound Indications for Use Form

Page 2 of 3

510(k) Number (if known): K060626

Device Name: VuMax 35 MHz transducer

Intended Use:
The *VuMax* 35 MHz transducer is for use with the VuMax ultrasound .

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic	P	P								P (3D)
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V **OR** **Over-the-Counter Use**____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060626

Diagnostic Ultrasound Indications for Use Form

Page 3 **of** 3

510(k) Number (if known): K060626

Device Name: VuMax 50 MHZ transducer

Intended Use:

The *VuMax* 50 MHz transducer is for use with the Vumax ultrasound system.

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic	P	P								P (3D)
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Nancy C Brogdon

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